IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC., a Delaware corporation, Plaintiff, v. DEXCOM, INC., a Delaware corporation, Defendant.	)	C. A. No. 05-590-GMS

REPLY IN SUPPORT OF ABBOTT'S MOTION TO TAKE LIMITED JURISDICTIONAL DISCOVERY BEFORE RESPONDING TO DEXCOM'S MOTION TO DISMISS

INTRODUCTION

In an apparent effort to insulate its allegations from challenge, DexCom is resisting all discovery relating to the factual arguments made in its motion to dismiss under Rule 12(b)(1). In this circuit, however, "either party should be allowed discovery on the factual issues raised by [a] motion" to dismiss on jurisdictional grounds. *Canavan v. Beneficial Finance Corp.*, 553 F.2d 860, 865 (3d Cir. 1977).

DexCom offers no good reason for departing from that general rule. It primarily argues that discovery is unnecessary because the FDA has not yet approved its product, which DexCom contends is an analysis-ending fact, automatically rendering all discovery unnecessary. But that argument contradicts DexCom's own approach to the issue (DexCom filed nine exhibits and an employee's affidavit while making various factual arguments beyond its lack of approval); it defies simple logic (any such rule would preclude all declaratory judgment actions

before FDA approval); and it ignores settled law (the Federal Circuit and district courts have routinely exercised declaratory jurisdiction before FDA approval).

The relevant question, which DexCom largely ignores, is whether there is a "practical likelihood" of infringing activity occurring in the near future. As Abbott expects discovery to confirm, FDA approval and, thus, infringing activity is not only a practical likelihood, it is a foregone conclusion. Based on public information alone, Abbott already knows that the FDA authorized an expedited approval process for DexCom's product, DexCom is seeking a specialized category of more easily-obtained FDA approval, the FDA has indicated no further clinical testing is necessary, DexCom already answered all the questions that the FDA posed in the 100-day meeting and DexCom itself expects FDA approval in the second quarter of 2006. All of this contradicts DexCom's main factual argument that FDA approval is impossible to predict with any confidence.

Based on the general rule authorizing jurisdictional discovery in these very circumstances, as well as common sense given DexCom's many factual arguments, Abbott is entitled to discovery to gather further facts confirming that FDA approval is a practical likelihood. DexCom does not claim it will be burdened or prejudiced by the limited discovery Abbott has requested and, thus, the Court should allow the discovery to proceed.

ARGUMENT

When initially asking this Court to consider the nine exhibits and employee affidavit it filed along with its motion to dismiss, DexCom recognized that "the court may receive evidence to resolve the jurisdictional factual dispute." (DexCom Mot. to Dis. Br. at 10, n. 6). Now, when it no longer suits its purposes, DexCom asserts that there is no reason to give Abbott access to contrary evidence. Nothing justifies that about-face, and none of the arguments that DexCom offers for resisting discovery have any merit.

A. Discovery Is Ordinarily Allowed When, As Here, A Party Challenges Jurisdictional Facts.

DexCom does not and cannot deny that discovery is normally allowed in these very circumstances. DexCom is specifically challenging the facts supporting jurisdiction. Under the law, "once the defendant has challenged jurisdictional facts, the court may receive evidence to resolve the factual dispute." *Interdigital Tech. Corp. v. OKI Am., Inc.*, 845 F. Supp. 276, 281 (E.D. Pa. 2004). As a necessary corollary, courts have "broad authority to order discovery" to gather that evidence. *Valentin v. Hosp. Bella Vista*, 254 F.3d 358, 363 (1st Cir. 2001).

Such discovery is presumptively allowed. As the Third Circuit explained, when jurisdiction is challenged, "either party should be allowed discovery on the factual issues raised by that motion." *Canavan*, 553 F.2d at 865; *Interdigital Tech. Corp.*, 845 F. Supp. at 281 (considering interrogatories answered by defendant when resolving 12(b)(1) motion); *Biogen, Inc. v. Shearing AG*, 954 F. Supp. 391 (D. Mass. 1996) ("[t]he court has great latitude to direct limited discovery and to make such factual findings as are necessary to determine its subject matter jurisdiction") (citing *Rivera-Flores v. Puerto Rico Telephone Co.*, 64 F.3d 742, 748 (1st Cir. 1995)).

This general rule applies here. Abbott has alleged that DexCom "has *already* conducted all the clinical trials necessary for approval" and publicly stated that it "expects FDA approval for marketing by the second quarter of 2006." (Abbott Complaint ¶¶ 13, 15) (emphasis added). DexCom, in contrast, has alleged that it cannot reliably predict when or whether the FDA will approve its product, arguing that whether it will obtain FDA approval is "unpredictable." (DexCom Br. at 2). It also asserts that the FDA may order more clinical trials. (*Id.* at 1). Allowing limited, non-burdensome discovery to shed light on these factual disputes is perfectly appropriate and, indeed, mandated by the case law. *See Canavan*, 553 F.2d at 865

(reversing dismissal on jurisdictional grounds due to the lack of discovery on the issue); *Commissariat A L'Energie Atomique v. Chi Mei Optoelectronics Corp.*, 395 F.3d 1315, 1323 (Fed. Cir. 2005) (reversing dismissal on personal jurisdictional grounds due to the lack of discovery on the issue).

B. Courts Routinely Entertain Declaratory Judgment Actions Before FDA Approval.

To attempt to avoid the rule permitting discovery, DexCom first argues that jurisdiction does not exist based on the simple fact that the FDA has not yet approved its product. (DexCom Br. at 1). But accepting that argument would automatically preclude declaratory judgment actions before the FDA approves an infringing product.

That obviously is not the law. DexCom does not contest that declaratory judgment actions are "proper even though there are future contingencies that will determine whether a controversy ever becomes real." WRIGHT & MILLER, 10 Fed. Pract. & Proc. Civ. 3d § 2757. To determine whether to exercise jurisdiction in such circumstances, courts simply "focus on the practical likelihood that the contingencies will occur." *E.R. Squibb & Sons, Inc. v. Lloyd's & Cos.*, 241 F.3d 154, 177 (2d Cir. 2001) (citing *Associated Indemnity Corp. v. Fairchild Industries, Inc.*, 961 F.2d 32 (2d Cir. 1992)); *Chevron U.S.A. Inc. v. Traillour Oil Co.*, 987 F.2d 1138, 1153 (5th Cir 1993) (same); *Seippel v. Jenkens & Gilchrist, P.C.*, 341 F. Supp. 2d 363, 383 (S.D.N.Y. 2004) (same); *Molitch v. Brotman*, No. Civ. A. 96-7742, 1997 WL 431008, at *2 (E.D. Pa. July 15, 1997) (noting that declaratory plaintiff need not establish that the prospect of injury "is a mathematical certainty" and, instead, jurisdiction is appropriate if the threat of future injury is "real and substantial."); WRIGHT & MILLER, 10 Fed. Pract. & Proc. Civ. 3d § 2757 (courts should look to the "practical likelihood that the contingencies will occur in determining whether an actual controversy exists").

That is equally true in patent cases. The accused infringer "need not have actually produced or be selling the product at issue as long as it has engaged in 'present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.'" *Biogen, Inc. v. Schering AG*, 954 F. Supp. 2d 391 (D. Mass. 1996) (citing *BP Chemicals Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993)).

Thus, the Federal Circuit and district courts routinely entertain declaratory judgment actions long before FDA approval. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997) (affirming jurisdiction existed 17 months before FDA approval); *Kos Pharm., Inc. v. Barr Labs, Inc.*, 242 F. Supp. 2d 311, 318 (S.D.N.Y. 2003) (affirming jurisdiction when FDA approval was about 16 months away); *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 08 (N.D. Ill. 2001) (affirming jurisdiction 13 to 19 months before FDA approval).

Indeed, filing for FDA approval is exactly the sort of "concrete steps taken with the intent to conduct [infringing] activity" the courts find sufficient to provide declaratory judgment jurisdiction. *See, e.g., Glaxo*, 110 F.3d at 1571 (affirming jurisdiction based on filing of FDA application); *Takeda Chem. Indus., Ltd. v. Watson Pharm., Inc.*, 329 F. Supp. 2d 394, 402 (S.D.N.Y. 2004) (upholding jurisdiction based on application filing alone because "applying for FDA approval, show[s] that [party] has taken significant steps towards manufacturing and testing its…products"); *Astra Aktiebolag v. Andrx Pharmaceuticals, Inc.*, 222 F. Supp. 2d 423, 525 (S.D.N.Y. 2002) ("there is no question that all Defendants seek or have obtained FDA approval to the proposed ANDA product within the near future; therefore, the actual controversy requirement is met and the declaratory judgment action will be entertained"); *Glaxo, Inc. v. Torpharm, Inc.*, No. 95 C 4686, 1997 WL 282742, at *3 (N.D. Ill. May 18, 1997) ("[s]ince there is no question that TorPharm seeks FDA approval to sell a [drug] in the near future, the actual controversy requirement will be entertained").

In support of its argument that FDA approval is required to support jurisdiction, DexCom relies exclusively on cases decided before the Federal Circuit's decision in *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir 1997), where the Court made it clear that FDA approval was *not* necessary for jurisdiction and, in fact, upheld jurisdiction even though FDA approval was 17 months away. And contrary to DexCom's position, no court has ever held that there is a special rule for medical device cases – as opposed to pharmaceutical cases – requiring FDA approval for jurisdiction. Instead, each of DexCom's cases simply holds that that it was too early in the application process to entertain jurisdiction. For instance, in *Telectronics Pacing Systems v. Ventritex*, the Federal Courted noted that the product "was *years away* from approval" and that the applicant "had only recently begun clinical trials." 982 F.2d 1520, 1527 (Fed. Cir. 1992) (emphasis added).

Here, in contrast, DexCom "has *already* conducted all the clinical trials necessary for approval" and publicly stated that it "expects FDA approval for marketing by the second quarter of 2006." (Abbott Complaint ¶¶ 13, 15) (emphasis added). Under the law, there are only two valid choices – either these factual assertions from Abbott's complaint "must be taken as true and viewed in the light most favorable to" Abbott or the Court should allow discovery so that DexCom's contrary assertions may be tested. *See Interdigital,* 845 F. Supp. at 281.

C. Discovery Should Confirm The Public Information Proving That DexCom's Approval Is Imminent.

DexCom next argues that discovery is not necessary because the "Court needs no citation" for the allegation that FDA approval is "unpredictable." (DexCom Br. at 2). Of course, this contention is belied by DexCom's decision to provide multiple "citation[s]" for that very allegation, including nine voluminous exhibits and an employee's affidavit. DexCom should not

be allowed to have it both ways – submitting evidence in support of its factual allegations and denying Abbott any access to information that contradicts the allegations.

In fact, through discovery, Abbott fully expects to prove that FDA approval of DexCom's product is not only a practical likelihood, but imminent. The public information, by itself, indicates that this is so. For instance, the FDA has granted expedited review of DexCom's product. (Abbott Complaint at ¶ 12). "Granting expedited review status means that a marketing application that is determined to be appropriate for expedited review is placed at the beginning of the appropriate review queue and receives additional review resources, as needed." (Exhibit A at Section C (Expedited Review Guidance from FDA)).

DexCom also already had a pivotal meeting with the FDA – called the 100-day meeting – where the FDA was supposed to "inform [DexCom] of any identified deficiencies and what information is required to correct those deficiencies…." (Exhibit B at 1). According to DexCom, the FDA did *not* identify any substantial deficiencies at that meeting. Instead, the FDA asked certain questions that DexCom "consider[ed] …. *readily answerable.*" (Exhibit C, (DexCom July 25, 2005 Press Release) (emphasis added)). Over six weeks ago, DexCom also announced that "expect[ed] to provide the requested information in an expeditious manner." (*Id*). And DexCom provided that to the FDA earlier this week. (Exhibit D, September 12, 2005 Press Release).

Although DexCom also now claims that the FDA may require more clinical trials, DexCom previously announced that the FDA "did *not* make any request for DexCom to conduct additional clinical studies" at the 100-day meeting. (Exhibit C (emphasis added)). On the contrary, DexCom has repeatedly stated that such clinical trials would *not* be necessary because it *already* "met [its] primary safety and efficacy end points" through its earlier clinical trials. (Exhibit E at 9) (Transcript of CEO Speech, June 23, 2005).

DexCom also "announced the successful completion of two key inspections related to the FDA review of the PMA application" (Exhibit F (DexCom August 2, 2005 Press Release). DexCom stated that "[s]uccessfully completing BIMO and QSR inspections is a very significant achievement for DexCom as we progress toward being a commercial enterprise capable of launching a product, ***especially as the inspections occurred earlier than we would have expected, only four months after filing our first-ever PMA.*** Since we filed our PMA application, we have continued to have a very interactive, timely and productive review process with the FDA." *Id.* (emphasis added)

FDA approval is all the more certain because, unlike Abbott, DexCom reportedly is seeking a lower-threshold approval called "adjunct" labeling as well as "replacement" labeling. Adjunct labeling means that DexCom's device would be used in conjunction with the traditional finger-stick testing and, thus, would be acting only as a "back-up" or "supplemental" method to a long-proven technology for measuring glucose levels. In contrast, as the term suggests, replacement labeling means the device would replace finger-sticking. Thus, Abbott's device would be the *only* method of measuring glucose for the patients. There will be no back-up system, making it all the more important that the device is fail safe. Not surprisingly, adjunct labeling is much more readily available than replacement labeling.

Despite all of these facts showing that DexCom's approval is a foregone conclusion, DexCom asserts that it cannot reliably predict whether it will obtain FDA approval. That assertion is not credible and therefore, discovery of DexCom's communications with the FDA as reflected in internal assessments is both appropriate and justified.

D. Contrary To DexCom's Conclusory Assertion, All Relevant Information Is Not Publicly Available.

DexCom additionally asserts that all the "material" facts are already "publicly available" and, thus, discovery is not necessary. (DexCom Br. at 1). That certainly is not true. In written and oral communications, the FDA routinely advises applicants about whether it has concerns that would place approval in jeopardy and, indeed, often indicates exactly what information is necessary to obtain approval. DexCom has not publicized the details of these communications, which could easily confirm the publicly-available information indicating that DexCom's approval is inevitable.

Indeed, DexCom's brief and affidavit contain specific allegations relating to recent communications with the FDA, which DexCom described only in the most general terms without any details about the FDA's specific statements. (DexCom's Mot. to Dis. Br. at 12). Based on these communications, DexCom knows exactly what issues remain outstanding before the FDA and also knows definitively whether those issues present any meaningful obstacle to approval. DexCom should not be permitted to hide that information while claiming that it cannot reliably predict whether it will obtain FDA approval.

DexCom also asserts that FDA approval is not assured because "DexCom has never announced that FDA approval is imminent." (DexCom Br. at 4). Regardless of whether it announced that fact, DexCom certainly knows whether approval is a practical likelihood, which is all that is required to establish jurisdiction. Thus, Abbott should be allowed to conduct the requested discovery to show that approval is, in fact, imminent.

Finally, DexCom suggests that Abbott should be forced to rely only on information that DexCom has chosen to publicly disclose because everything else is "highly sensitive, valuable proprietary information…." (DexCom's Br. at 4). Obviously, a protective

order can eliminate that concern and Abbott is certainly willing to agree to a reasonable protective order. But in its zeal to resist all discovery, DexCom has not even requested one. *See e.g., Lamoureux v. Genesis Pharmacy Services, Inc.*, 226 F.R.D. 154, 162 (D. Conn. 2004). ("While Rule 26(c)(7) of the Federal Rules of Civil Procedure provides that a party may apply for a protective order regarding 'confidential research, development, or commercial information,' no motion for a protective order is before the court. As such, it declines to entertain the merits.")

For these reasons, the Court should enter an order authorizing Abbott to proceed with its proposed discovery.

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CERTIFICATE OF SERVICE

I hereby certify that on September 16, 2005, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

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